



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Takashi Shigematsu et al. Art Unit : 1641
Serial No. : 10/009,151 Examiner : Kartic Padmanabhan
Filed : November 30, 2001
Title : STABILIZED DENATURED LIPOPROTEIN AND PROCESS FOR
PRODUCING THE SAME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF AVAILABILITY

I, Y. Rocky Tsao, hereby declare:

1. I am an attorney of record in the above-captioned patent application.
2. Kyowa Medex Co., LTD (1-1, Irifune 2-Chome, Chuo-ku, Tokyo 104-0042, Japan) is the assignee of the entire right, title and interest in the invention described and claimed in the above-captioned patent application.
3. Under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure, one strain of this invention, was deposited on May 26, 2000 with the National Institute of Bioscience and Human-Technology, 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki 305-8566, Japan, where it was given Accession Number NIBH FERM BP-7171. The strain was originally deposited on February 17, 1994. A request to change the conditions of the original deposit to follow those of a deposit under the Budapest Treaty was received by the depository on May 26, 2000. See the attachment.
4. Kyowa Medex Co., LTD agrees that upon allowance and issuance of the above-captioned patent application as a United States Patent, all restrictions on the availability to the

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposit Oct. 31, 2005
Signature Deborah R. Nast

Deborah R. Nast

Typed or Printed Name of Person Signing Certificate

public of the deposit will be irrevocably removed, and until such time, the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

5. Kyowa Medex Co., LTD further agrees that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited material, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer and that the deposited material will be replaced if the depository should be unable to furnish a sample when requested due to the condition of the deposit, such as inviability, contamination, or loss of capability to function in the manner described in the specification.

6. All statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: 10-31-05

Y. Rocky Tsao
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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

[特許手続上の微生物の寄託の国際的承認
に関するブダペスト条約]

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

下記国際寄託当局によって規則7.1に従い
発行される。issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this
page.

原寄託についての受託証

氏名 (名称)

株式会社ベッセルリサーチ・ラボラトリー
代表取締役社長 中村 寛之助

寄託者

あて名 〒

殿

東京都町田市旭町3丁目6番6号

1. 微生物の表示

(寄託者が付した識別のための表示)

Mouse-Mouse hybridoma FOH1a/DLH3

(受託番号)

FERM BP- 7171

2. 科学的性質及び分類学上の位置

1 桶の微生物には、次の事項を記載した文書が添付されていた。

- 科学的性質
- 分類学上の位置

3. 受領及び受託

本国際寄託当局は、平成 6 年 2 月 17 日 (原寄託日) に受領した1桶の微生物を受託する。

4. 移管請求の受領

本国際寄託当局は、平成 6 年 2 月 17 日 (原寄託日) に1桶の微生物を受領した。
そして、平成 12 年 5 月 26 日 に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。
(平成 6 年 2 月 17 日 に寄託された微工研菌寄第P- 14153 号より移管)

5. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

名称: National Institute of Advanced Industrial Science and Technology
Bioscience and Human-Technology
Agency for Industrial Science and Technology

所長 大箸 恒

Dr. Shigeaki Ohsaka Director-General

あて名: 日本国茨城県つくば市東1丁目1番3号 (郵便番号305-8566)

1-3, Higashi 1 chome Tsukuba-shi Ibaraki-ken
305-8566, JAPAN

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page.

DEPOSITOR:

Name: VESSEL RESEARCH LABORATORY CO., LTD.

Kannosuke NAKAMURA, Representative

Address: 6-6, Asahimachi 3-chome, Machida-shi, Tokyo

| | |
|---|-----------------------------------|
| 1. IDENTIFICATION OF THE MICROORGANISM | |
| Identification reference given by the DEPOSITOR Mouse-Mouse hybridoma FOH1a/DLH3 | Accession number: FERM BP-7171 |
| 2. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION | |
| The microorganism identified under 1. above was accompanied by: (x) a scientific description (x) a proposed taxonomic designation | |
| 3. RECEIPT AND ACCEPTANCE | |
| This International Depositary Authority accepts the microorganism identified under 1. above, which was received by it on 1994-02-17 (Date of the original deposit). | |
| 4. RECEIPT OF REQUEST FOR CONVERSION | |
| The microorganism identified under 1. above was received by this International Depositary Authority on 1994-02-17 and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on 2000-05-26. (Conversion from P-14153 deposited on 1994-02-17.) | |
| 5. INTERNATIONAL DEPOSITARY AUTHORITY | |
| Name: National Institute of Bioscience and Human-Technology Agency of Industrial Science and Technology Dr. Shinichi Ohashi Director-General (seal) Address: 1-3, Higashi 1 chome Tsukuba-shi Ibaraki-ken 305-8566, JAPAN | |

May 26, 2000

| | | |
|-------|--|---|
| 0-1 | 様式-PCT/RO/134 (EASY) この寄託された微生物又はその他の生物材料に関する表示 (PCT規則13の2)は、 右記によって作成された。 | PCT-EASY Version 2.90 (updated 10.05.2000) |
| 0-1-1 | | |
| 0-2 | 国際出願番号。 | |
| 0-3 | 出願人又は代理人の書類記号 | F2000-38-PCT |

| | | |
|-------|---|------------------------------|
| 1 | 下記の表示は発明の詳細な説明中に記載された微生物又は生物材料に関連している。 | |
| 1-1 | 記載頁 | 15 |
| 1-2 | 行 | 24 |
| 1-3 | 寄託の表示 | |
| 1-3-1 | 寄託機関の名称 | 通商産業省・工業技術院生命工学工業技術研究所(NIBH) |
| 1-3-2 | 寄託機関のあて名 | 日本国 〒305-8566 茨城県つくば市東1丁目1-3 |
| 1-3-3 | 寄託の日付 | 2000年05月26日 (26.05.2000) |
| 1-3-4 | 受託番号 | NIBH FERM BP-7171 |
| 1-4 | 追加の表示 | なし (NONE) |
| 1-5 | この表示を行うための指定国 | すべての指定国 |
| 1-6 | 追加事項の表示の届け出 右記の表示は後に国際事務局に届け出る予定である。 | なし (NONE) |

受理官庁記入欄

| | | |
|-------|-------------------------------|--|
| 0-4 | この用紙は国際出願とともに受理した (はい/いいえ) | |
| 0-4-1 | 権限のある職員 | |

国際事務局記入欄

| | | |
|-------|-------------------|--|
| 0-5 | この用紙が国際事務局に受理された日 | |
| 0-5-1 | 権限のある職員 | |

PCT

F2000-38-PCT

| | | |
|-------|--|--|
| 0-1 | Form - PCT/RO/134 (EASY) Indications Relating to Deposited Microorganism(s) or Other Biological Material (PCT Rule 13bis) | |
| 0-1-1 | Prepared using | PCT-EASY Version 2.90 (updated 10.05.2000) |
| 0-2 | International Application No. | |
| 0-3 | Applicant's or agent's file reference | F2000-38-PCT |
| 1 | The indications made below relate to the deposited microorganism(s) or other biological material referred to in the description on: | |
| 1-1 | page | 15 |
| 1-2 | line | 24 |
| 1-3 | Identification of Deposit | |
| 1-3-1 | Name of depositary institution | National Institute of Bioscience and Human-Technology Agency of Industrial Science and Technology |
| 1-3-2 | Address of depositary institution | 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki 305-8566 Japan |
| 1-3-3 | Date of deposit | 26 May 2000 (26.05.2000) |
| 1-3-4 | Accession Number | NIBH FERM BP-7171 |
| 1-4 | Additional Indications | NONE |
| 1-5 | Designated States for Which Indications are Made | all designated States |
| 1-6 | Separate Furnishing of Indications These indications will be submitted to the International Bureau later | NONE |

FOR RECEIVING OFFICE USE ONLY

| | | |
|-------|--|--|
| 0-4 | This form was received with the International application: (yes or no) | |
| 0-4-1 | Authorized officer | |

FOR INTERNATIONAL BUREAU USE ONLY

| | | |
|-------|---|--|
| 0-5 | This form was received by the International Bureau on: | |
| 0-5-1 | Authorized officer | |